UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

John G. Miller,

Civil No. 11-115 (DWF/LIB)

On behalf of himself and all others similarly situated,

Plaintiff,

v.

MEMORANDUM OPINION AND ORDER

Redwood Toxicology Laboratory, Inc.,

Defendant.

A. L. Brown, Esq., The Law Offices of A. L. Brown; Andrew L. Davick, Esq., and Anthony J. Nemo, Esq., Meshbesher & Spence, Ltd.; and Joshua R. Williams, Esq., The Law Office of Joshua R. Williams, PLLC, counsel for Plaintiff.

Hal A. Shillingstad, Esq., Andrea D. Kiehl, Esq., and Ashley A. Wenger, Esq., Ogletree, Deakins, Nash, Smoak & Stewart, P.C., counsel for Defendant.

INTRODUCTION

This matter is before the Court on a "Motion for Temporary Restraining Order,

Preliminary Injunction, [and] Expedited Discovery" brought by Plaintiff John G. Miller.

Miller seeks an order enjoining Defendant Redwood Toxicology Laboratory, Inc.

("Redwood") from directly or indirectly stating, claiming, professing, indicating, or

otherwise communicating to any consumer certain statements regarding an alcohol

screening test that Redwood performs. For the reasons set forth below, Miller's motion is

denied.

BACKGROUND

Redwood is a Florida corporation with its principal place of business in California. (First Am. Compl. ¶ 2.) Its primary business is the operation of forensic drug testing facilities. (*Id.*) Redwood performs numerous toxicological drug and alcohol tests, including EtG/EtS urine tests at the request of customers nationwide. (Decl. of Wayne Ross ("Ross Decl.") ¶ 2.) Redwood's scientific procedures, documentation, and personnel are licensed by the U.S. Department of Health and Human Services ("DHHS"). (*Id.* ¶ 7.)

EtG/EtS testing involves the measurement of EtG (ethyl glucuronide) and EtS (ethyl sulfate), two direct metabolites from ethanol that can be found in urine up to three to four days after ethanol is ingested. (*Id.* ¶ 3.) Ethanol is a chemical compound found in various products, including fermented alcohol products such as beer, wine, and distilled liquors. (*Id.* ¶ 4.) Ingestion encompasses the presence of the ethanol compound in the body from any means or source whether oral, inhaled, or dermal, whereas consumption refers more exclusively to oral consumption or drinking. (*Id.* ¶ 5.) The only way a test subject can have EtG or EtS in the urine is if ethanol has been ingested. (*Id.* ¶ 16.) An EtG level over 100 ng/mL and EtS level over 25 ng/mL indicates exposure to ethanol but is not dispositive of intentional consumption of alcohol. (*Id.* ¶ 17.)

Miller is a recovering alcoholic. (Aff. of John G. Miller ("Miller Aff.") ¶ 1.) In January 2008, he was placed on supervised probation until January 2015. (*Id.* ¶ 2.) One of the conditions of his probation is that Miller may not use or possess alcohol, and he is therefore subject to random alcohol testing. (*Id.*) On or around March 6, 2010, Miller

suffered a relapse which led to the filing of a probation violation. (*Id.* ¶ 3.) Miller initially denied, but later admitted, the March 6 violation. ((Decl. of Joshua R. Williams ("Williams Decl.") ¶ 4, Ex. F at ¶ 3.) Miller's probation was reinstated on May 10, 2010. (*Id.*)

On June 15, 2010, Miller's probation agent required him to submit a urine sample. (Miller Aff. ¶ 6.) That sample was sent to Redwood for testing, and Redwood reported that the sample was positive for EtG with a level of 1130 ng/mL and positive for EtS with a level of 603 ng/mL. (*Id.* ¶ 7.) Miller denies that he drank any alcohol. A probation violation was filed against Miller, and he was arrested on or about June 23, 2010. (*Id.* ¶ 7, 9.) Miller's probation violation hearing was originally scheduled for July 26, 2010, but was twice continued¹ and ultimately occurred on September 29, 2010. (*Id.* ¶¶ 12-14.)

At the hearing, Miller testified that in the days before he provided his urine sample he assisted his mother in closing up a gift shop by cleaning metal shelving with a lacquer thinner which contained an alcohol substance. (Williams Decl. ¶ 4, Ex. F at ¶ 5.) Miller testified that there were heavy fumes from the thinner and no ventilation in the room. (*Id.*) Miller also testified that on or about June 13, 2010, his father went to the emergency room with a broken hip, and that between June 13 and June 15 Miller used hand sanitizer containing an alcohol substance at the hospital several times. (*Id.*)

The State of Minnesota called John Martin to testify at the probation violation hearing. Martin is a toxicologist and a technical consultant and certifying scientist at

¹ The record before the Court is silent as to (1) who requested the continuances, (2) the reason for the continuances, and (3) whether the continuances were granted with or without objection.

Redwood. (Williams Decl. ¶ 2, Ex. A at 3.) Martin testified that "there is considerable discussion concerning what is a good cutoff and whether there truly is one that could absolutely delineate between exposure to secondary products and exposure to only ethanol." (*Id.* at 21.) When asked if he was "aware of any scientific literature or papers regarding EtG or EtS testing which indicate that the incidental use in and of itself can result in EtG levels in excess of a thousand nanograms per milliliter," Martin testified that "as far as those articles that have been reviewed, the highest levels that I've seen indicated are one was 713." (*Id.* at 15.)

Miller called Dr. Gregory Skipper to testify at the probation violation hearing. Dr. Skipper is the medical director of the Alabama Physician Health program (the "Alabama Program"), which intervenes on and monitors troubled physicians in Alabama. (Williams Decl. ¶ 5, Ex. G at 3.) Dr. Skipper testified that he was instrumental in bringing EtG testing to the United States. (*Id.* at 5.) Dr. Skipper uses EtG/EtS testing as a tool to ensure compliance for doctors in the Alabama Program. (*Id.* at 8-9.) Dr. Skipper testified that in his opinion there was no agreed upon or known cutoff level for EtG levels to indicate that somebody has been drinking. (*Id.* at 19.) He testified that a study that involved using hand gel every two minutes for an hour in a closed room resulted in levels up to nearly 800 ng/mL, that a pharmacist using hand gel every half hour throughout the day produced a result of 770, and that a doctor "that fairly certainly had only used topical alcohol on joints" had a level of 1500. (*Id.* at 16, 20.)

When a subject in the Alabama Program directed by Dr. Skipper has a positive EtG/EtS test and denies drinking, a second test, called phosphatidyl ethanol, is performed

to confirm drinking. (*Id.* at 9.) Dr. Skipper testified that about ten or fifteen percent of positive EtG/EtS tests have a negative result on the phosphatidyl ethanol test. (*Id.* at 10.) Dr. Skipper also testified that the phosphatidyl ethanol test only produces a positive result if a person has consumed about seven standard drinks within a week. (*Id.* at 24-25.)

The state court found that Miller had credibly presented evidence of incidental exposure to alcohol and the State of Minnesota had not met its burden of proving that Miller had violated his probation by clear and convincing evidence. (Williams Decl. ¶ 4, Ex. F at ¶¶ 3, 10.)

On January 18, 2011, Miller filed a lawsuit against Redwood, alleging seven causes of action. (Doc. No. 1.) Miller later amended the Complaint to allege a proposed class action. (Doc. No. 5.) The First Amended Complaint asserts three causes of action: violation of Minnesota False Statement in Advertising Act ("FSAA"), Minn. Stat. § 325F.67; violation of Minnesota Consumer Fraud Act ("CFA"), Minn. Stat. § 325F.69; and negligence.

On April 20, 2011, Redwood filed a motion to dismiss with a hearing date of July 22, 2011. (Doc. No. 11.) On April 25, 2011, Miller filed the current "Motion for Temporary Restraining Order, Preliminary Injunction, [and] Expedited Discovery." (Doc. No. 13.) In this motion, Miller seeks an order enjoining Redwood from directly or indirectly stating, claiming, professing, indicating or otherwise communicating to any consumer that Redwood's EtG/EtS test is ideal for zero tolerance and abstinence situations, produces highly accurate results, and that the test's analytical methods are approved by the U.S. Department of Health and Human Services. The parties agreed to a

briefing schedule, and the Court held a hearing on May 17, 2011, with both parties present and represented by counsel.

DISCUSSION

I. Legal Standard

Under Eighth Circuit precedent, a preliminary injunction may be granted only if the moving party can demonstrate: (1) a likelihood of success on the merits; (2) that the movant will suffer irreparable harm absent the restraining order; (3) that the balance of harms favors the movant; and (4) that the public interest favors the movant. *See Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981). None of the factors by itself is determinative; rather, in each case, the factors must be balanced to determine whether they tilt toward or away from granting injunctive relief. *See West Pub. Co. v. Mead Data Cent., Inc.*, 799 F.2d 1219, 1222 (8th Cir. 1986). The party requesting the injunctive relief bears the "complete burden" of proving all of the factors listed above. *Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 418 (8th Cir. 1987).

A. Likelihood of Success on the Merits

The first *Dataphase* factor requires that the movant establish a substantial probability of success on the merits of its claim. *See Dataphase*, 640 F.2d at 114. Miller asserts that there is a significant likelihood that he will succeed on the merits of his claims under the CFA and FSAA.² The CFA provides, in relevant part, as follows:

The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive

² Miller does not assert his negligence claim as a basis for the requested injunctive relief.

practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable as provided in section 325F.70.

Minn. Stat. § 325F.69. The FSAA provides, in relevant part, as follows:

Any person, firm, corporation, or association who . . . makes, publishes, disseminates, circulates, or places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public . . . an advertisement of any sort . . . which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

Minn. Stat. § 325F.67.

An individual bringing a claim under the CFA or FSAA must do so through the Private Attorney General Statute, Minn. Stat. § 8.31. *Group Health Plan, Inc. v. Philip Morris, Inc.*, 621 N.W.2d 2, 8 (Minn. 2001). The Private Attorney General Statute provides that any person injured by a violation of the CFA or FSAA may bring a private action and recover damages. *Id.* Individuals bringing a claim through the Private Attorney General Statute must "demonstrate that their cause of action benefits the public." *Ly v. Nystrom*, 615 N.W.2d 302, 314 (Minn. 2000).

Miller asserts that a significant likelihood exists that he will succeed on the merits because Redwood's advertisements and other statements about the EtG/EtS test are misleading. In particular, Miller contends that the following statements mislead the public into believing that an EtG level of 100 ng/mL and EtS level of 25 ng/mL are dispositive of intentional consumption of alcohol: "Are they drinking? We'll find out"; "We deliver the certainty of science, the dependability of proven drug screening processes and the assurance of legally defensible results"; "Ideal for zero tolerance and abstinence situations"; and "Any EtG level over 100 ng/mL and EtS level over 25 mg/mL indicates exposure to ethanol."

Miller also asserts that Redwood's statement that "[t]he analytical methods used by RTL are scientifically accepted and approved by the U.S. Department of Health and Human Services" misleads the public into believing that Redwood's EtG/EtS test and cutoffs are sanctioned by the U.S. Department of Health and Human Services ("DHHS"). Miller argues that this is false and relies on a 2006 Advisory from the Substance Abuse and Mental Health Services Administration ("SAMHSA") within DHHS which states the following: Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this *Advisory*, is inappropriate and scientifically unsupportable at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature.³

(Williams Decl. ¶ 6, Ex. H at 1.)

Miller asserts that prosecutors and probation officers around the country often seek the imposition of criminal penalties based solely on Redwood's test results, and that, but for Redwood's misrepresentations and misleading statements concerning the quality and reliability of its EtG/EtS test, no one would use the test to determine whether to take legal or disciplinary action against a subject.

(Williams Decl. ¶ 2, Ex. A at 21.)

³ When questioned regarding the 2006 Advisory at Miller's probation violation hearing, John Martin testified as follows:

[[]S]ince that time there have been numerous articles published and there's been a considerable change from that advisory forward as far as determining what a reasonable cutoff would be given that there are all of these products that do contain ethanol and can then form EtG. And even following Dr. Skipper through time, there are a number of different recommendations dependent on where it was in the time frame from 2006 to the present time and that's what I'm saying. At one time he recommended a cutoff of 250 and then in conjunction with Paul Cary, they recommended a cutoff of 500. I believe in some of his—on his website or in some current literature, he recommends a cutoff of 1,000 up to 1,500. I mentioned that earlier. And so there is considerable discussion concerning what is a good cutoff and whether there truly is one that could absolutely delineate between exposure to secondary products and exposure to only ethanol.

Redwood responds that the statements at issue are not false and misleading and do not support a misrepresentation claim. Redwood asserts that the tagline "Are they drinking? We'll find out" and the use of the word "ideal" are mere puffery and therefore non-actionable. Redwood asserts that the remaining statements are factually accurate. Redwood also contends that there is no causal nexus between Redwood's alleged misrepresentations and Miller's incarceration and that there is no evidence of detrimental reliance by any Redwood customer. Redwood asserts in addition that Miller's CFA and FSAA claims fail because Miller cannot establish that the pursuit of his claims benefits the public at large and therefore Miller lacks standing under the Private Attorney General Statute.

The Court concludes that Miller has failed to demonstrate a likelihood of success on the merits of his CFA and FSAA claims. At the core of Miller's assertions is the argument that Redwood misleads the public into believing that its EtG/EtS test, with cutoff levels of 100 ng/mL of EtG and 25 ng/mL of EtS, is dispositive as to intentional consumption of beverage alcohol. The Court notes, however, that the very exhibits relied upon by Miller include the following under "Frequently Asked Questions":

How accurate and reliable is the EtG/EtS test?

EtG/EtS are direct metabolites of alcohol (ethanol), and their detection in urine is highly specific, similar to testing for other drugs. . . . As is the case with any laboratory test, it is also very important to obtain clinical correlation.

. . .

Will the use of incidental alcohol, such as mouthwash and Over-the-Counter (OTC) cough syrups trigger a positive result?

Tests show that "incidental exposure" to the chronic use of food products (vanilla extract), hygiene products, mouthwash, or OTC medications (cough syrups), which contain ethanol, can produce EtG concentrations in excess of 100 ng/mL. However, if measurable ethanol is detected (>.04 gm %) in the urine, and EtG is detected in excess of 100 ng/mL and EtS is also detected in excess of 25 ng/mL, then this is very strong evidence that beverage alcohol was ingested.

(Williams Decl. ¶ 3, Ex. E at 2 (emphasis in original).) Redwood's website also contains a copy of its current Certificate of Compliance issued by the Centers for Medicare & Medicaid Services within DHHS. (Ross Decl. ¶ 7, Ex. 1.) This record does not demonstrate a likelihood of success on Miller's claim that Redwood's statements are false or misleading.

Even if the Court were to view the record in the light most favorable to Miller, Redwood's statements would still not constitute actionable conduct. To succeed on his CFA and FSAA claims, Miller must demonstrate that he was injured by Redwood's alleged misrepresentations. The Minnesota Supreme Court has explained that in order to prove a claim for damages under the CFA or FSAA, a plaintiff "must establish a causal nexus between their alleged damages and the conduct of the defendants alleged to violate the statutes. This causal nexus has a component of reliance" *Group Health Plan*, 601 N.W.2d at 15. The current record contains no evidence that Redwood's statements have been relied upon. Even if Miller's test result was the sole cause of his detention, the record before the Court does not show that it was Redwood, as opposed to a probation officer, the state court, or even Miller himself, that either caused the initial detention or caused the detention to continue for 135 days.

B. Irreparable Harm

Miller must establish that irreparable harm will result if injunctive relief is not granted and that such harm will not be compensable by money damages. *See Packard Elevator v. I.C.C.*, 782 F.2d 112, 115 (8th Cir. 1986). A showing of speculative harm is insufficient to meet this burden. *Id.* Failure to show irreparable harm alone is a sufficient basis for a court to deny injunctive relief. *Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 420 (8th Cir. 1987).

Miller asserts that he will suffer irreparable injury absent the requested injunctive relief because he is facing the loss of freedom based solely on an inherently faulty test. Miller contends that at least ten percent of Redwood's EtG/EtS tests result in a false positive, which, in Miller's case, would be almost certain to lead to additional incarceration. Redwood asserts that Miller cannot show an actual, cognizable likelihood that he is subject to any action by Redwood that would affect him. Redwood argues that prospective harm some time in the future that may or may not happen does not constitute irreparable harm and that Miller's mere speculation is insufficient to warrant the extraordinary relief requested.

The Court concludes that on the current record Miller has not shown that irreparable harm will result if the requested relief is not granted. The record does not establish that Miller's incarceration was solely the result of a positive result on his EtG/EtS test. Miller has also not demonstrated that he is at risk of being incarcerated in the future based solely on a positive EtG/EtS test result. In addition, even if Miller had established such a risk, he has not demonstrated that the requested relief would eliminate

the alleged threat of harm. The relief requested by Miller would not stop Redwood from performing EtG/EtS testing in the future. It would prevent Redwood from making certain statements, but Miller has not shown that any of those statements were relied upon so as to cause his incarceration.

C. Balance of Harms and Public Interest

Because the Court finds that Miller has demonstrated neither a likelihood of success on the merits nor a threat of irreparable harm, the Court need not address the two remaining *Dataphase* factors.

For the reasons stated, **IT IS HEREBY ORDERED** that:

Plaintiff John G. Miller's Motion for Temporary Restraining Order,
Preliminary Injunction, Expedited Discovery (Doc. No. [13]) is **DENIED.**

Dated: May 25, 2011

<u>s/Donovan W. Frank</u> DONOVAN W. FRANK United States District Judge